Program to Evaluate Intravenous and Oral Ganaxolone in Patients with Severe or Moderate Postpartum Depression

RADNOR, Pa., June 27, 2017 (GLOBE NEWSWIRE) -- Marinus Pharmaceuticals, Inc. (Nasdaq:MRNS), a biopharmaceutical company dedicated to the development of innovative therapeutics to treat epilepsy and neuropsychiatric disorders, today announced that it has initiated its Phase 2 double-blind, placebo-controlled clinical trial to evaluate the safety, efficacy and pharmacokinetics (PK) of ganaxolone IV in women diagnosed with severe postpartum depression (Magnolia study). The clinical development plan with ganaxolone in postpartum depression (PPD) includes the Magnolia study, along with the soon to be initiated study to evaluate ganaxolone oral capsules in moderate PPD patients (Amaryllis study). PPD is a debilitating neuropsychiatric disorder that occurs following childbirth and can severely affect a mother's ability to care for her child. Data from the initial cohort in the Magnolia study are expected in the second half of 2017.

"Initiating this trial in women with postpartum depression is an important milestone for Marinus as we expand the therapeutic reach of ganaxolone into neuropsychiatric disorders," commented Christopher M. Cashman, Chief Executive Officer of Marinus Pharmaceuticals. "Postpartum depression occurs in one out of nine women who have given birth. We believe there is a strong mechanistic rationale for ganaxolone to provide a meaningful therapeutic benefit to these mothers struggling with PPD for which there are no approved therapies."

The Magnolia Study is a Phase 2 double-blind, placebo-controlled, multiple-dose escalation study that will be conducted at approximately 15 sites in the United States. The study will consist of multiple cohorts of women with a Hamilton Depression Rating Scale (HAMD17) score ≥26 randomized into each cohort. The study will evaluate the safety, efficacy and PK of ganaxolone in women with severe PPD. Patients randomized to the first study cohort will undergo an infusion of either ganaxolone or placebo. Patients will be followed for at least 30 days. Subsequent cohorts could include shorter or higher dose intravenous regimens alone or in sequential administration with oral ganaxolone. Data from the first cohort of patients are expected in the second half of 2017.

Dr. Lorianne Masuoka, Chief Medical Officer of Marinus Pharmaceuticals commented, "We are excited to kick-off our first clinical trial in PPD. We have optimized our development strategy for PPD to differentiate ganaxolone from other products in development for this severe, debilitating disease. We are planning to study both the intravenous and oral formulations of ganaxolone to provide various treatment options for mothers suffering from moderate to severe postpartum depression."

PPD is thought to be triggered in women when they experience rapid changes in the levels of endogenous neurosteroids during pregnancy. Plasma levels of allopregnanolone, a metabolite of progesterone and an endogenous $GABA_A$ modulator, are known to increase throughout pregnancy and then precipitously drop after delivery. There are also data suggesting that the sensitivity of the GABA system is altered during pregnancy and after childbirth, possibly due to changes in circulating neurosteroid levels, leading to highly symptomatic neurosteroid withdrawal after pregnancy. Ganaxolone, a precisely engineered analog of allopregnanolone and positive allosteric $GABA_A$ modulator, may alleviate PPD by increasing neurosteroid activity. This engineering modification prevents ganaxolone from being converted back to progesterone, a hormone which may not be beneficial in this condition.

About Postpartum Depression

Postpartum depression (PPD) is a neuropsychiatric disorder with no approved therapies that occurs in women following the birth of a child. According to the Center for Disease Control (CDC), PPD affects 10-15% of mothers within the first year of childbirth. Common symptoms include feelings of extreme sadness, hopelessness, suicidal ideation, thoughts of harming the baby, anxiety, and fatigue. PPD can affect a mother's ability to care for and bond with her child and may negatively affect a child's cognitive development. There are no approved treatments for PPD.

About Ganaxolone

Ganaxolone, a positive allosteric modulator of $GABA_A$, is being developed in three different dose forms (intravenous, capsule, and liquid) intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Unlike benzodiazepines, ganaxolone exhibits antiseizure and antianxiety actions via its effects on synaptic and extrasynaptic $GABA_A$ receptors. Ganaxolone has been studied in more than 1,500 subjects, both pediatric and adult, at therapeutically relevant dose levels and treatment regimens for up to two years. In these studies, ganaxolone was generally safe and well-tolerated. The most commonly reported adverse events were somnolence, dizziness and fatigue.

About Marinus Pharmaceuticals

Marinus Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to the development of ganaxolone, which offers a new mechanism of action, demonstrated efficacy and safety, and convenient dosing to improve the lives of patients suffering from epilepsy and neuropsychiatric disorders. Ganaxolone is a positive allosteric modulator of $GABA_A$ that acts on a well-characterized target in the brain known to have both antiseizure and antianxiety effects. Ganaxolone is being developed in three different dose forms (IV, capsule and liquid) intended to maximize therapeutic reach to adult and pediatric patient populations in both acute and chronic care settings. Marinus is currently evaluating ganaxolone in women with PPD and in orphan pediatric indications for the treatment of genetic seizure and behavior disorders, and preparing to initiate Phase 2 studies in status epilepticus, an orphan indication. For more information visit www.marinuspharma.com. Please follow us on Twitter: @MarinusPharma.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Marinus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may", "will", "expect", "anticipate", "estimate", "intend", "believe", and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding our interpretation of preclinical studies, development plans for our product candidate, including the development of dose forms, the clinical trial testing schedule and milestones, the ability to complete enrollment in our clinical trials, interpretation of scientific basis for ganaxolone use, timing for availability and release of data, the safety, potential efficacy and therapeutic potential of our product candidate and our expectation regarding the sufficiency of our working capital. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or

achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the conduct of future clinical trials, the timing of the clinical trials, enrollment in clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, and other matters, including the development of formulations of ganaxolone, that could affect the availability or commercial potential of our drug candidates. Marinus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see filings Marinus has made with the Securities and Exchange Commission.

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